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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,824	08/31/2006	Richard P. Phipps	176/61654(1247)	9061

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EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,824	PHIPPS ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-37,56-65 and 106-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-37,56-65 and 106-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/26/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 10/09/2007. Claim(s) 17-37 and 56-65 are pending. Claim(s) 106-108 have been added. Claim(s) 17-37, 56-65 and 106-108 are examined herein.

Response to Arguments

Applicant's arguments with respect to the112 1st rejection of claims 27-37 have been fully considered but are not persuasive. Applicants argue that "...Examples 6 and 8 fully supports the prophylactic method..." This is not persuasive because a "blunting" of platelet activity is not considered to be enabled for "preventing a thrombic condition". The specification specifically discusses said results as having "...largely prevented..." CD40L and TXB_2 release (page 38, line 25) and "...substantially prevented..." thrombin –induced release of PGE_2 (page 38, line 28). Thus the rejection is hereby maintained and is restated below for Applicants' convenience.

Applicants arguments with respect to the112 2nd rejection of claims 23-25, 33-35 and 62-65 have been fully considered but are not persuasive. There is no antecedent basis of the instant claims for "an inducer of a PPARγ agonist" in claim 17. The rejection is hereby maintained and is restated below for Applicants' convenience.

Applicant's arguments with respect to the 103(a) rejection of claims 17-23, 25, 27-33, 35, 37, 56-62, and 64 as being unpatentable over Pershadsingh (US Patent No.

6,127,394) in view of Boyer (US Patent 7,018,985 B1) have been fully considered but are not persuasive.

Applicant argues that Pershadsingh "identifies a class of thiazolidinedione derivatives and indicated that the compounds are activators of PPARγ... although other portions of the reference are unclear whether these compounds are agonists or antagonists of PPARγ."

This argument is not persuasive. If the compounds of the prior art are the same, then they will necessarily possess the same properties as those set forth in the instant application.

Furthermore, Applicant argues that Pershadsingh identifies thrombosis in a long list of diseases. Applicant contends that it was not known that platelets possessed the nuclear receptor PPARγ and that persons of ordinary skill in the art would have no basis to expect that contacting a platelet with a PPARγ agonist would have any effect at all.

This argument is not persuasive because discovering an unappreciated property of a prior art does not render the new function patentable. It is noted that, "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.,* 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is present but unknown in the prior art does not necessarily make the claim patentable. The fact that Pershadsingh teaches a method of treating PPARγ mediated diseases (claim 29) of which thrombosis is encompassed by would

motivated one in the art to try, with a reasonable degree of success, treating thrombosis with a PPARγ agonist.

Applicant's arguments with respect to the 103(a) rejection of claims 24, 26, 34, 36, 63 and 65 as being unpatentable over Pershadsingh (US Patent No. 6,127,394) in view of Boyer (US Patent 7,018,985 B1) as applied to claims 17-23, 25, 27-33, 35, 37, 56-62, and 64 above in further view of Höök (US Patent No. 6,413,931 B1) have been fully considered but are not persuasive.

Applicants argue that Höök fails to teach the new use of decorin. This is not persuasive. As mentioned above "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.,* 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is present but unknown in the prior art does not necessarily make the claim patentable.

The rejections are hereby maintained and modified as necessitated by amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-37 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the treatment of a thrombotic condition or disorder, does not reasonably provide enablement for the prevention of a thrombotic condition or disorder as recited in these claims.

The instant claims are drawn to a method for the prevention of a thrombotic condition or disorder. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention:

The instant invention pertains to a method for the prevention of a thrombotic condition or disorder.

The state of the prior art:

The skilled artisan would view that the prevention of one or more symptoms of a thrombotic condition or disorder totally, absolutely, or permanently, is highly unlikely, since one cannot guarantee that the thrombotic condition or disorder will always be prevented.

The relative skill of those in the art:

The relative skill of those in the art is very high.

The predictability or lack thereof in the art:

The skilled artisan would view that the treatment to prevent a thrombotic condition or disorder, absolutely, or permanently is highly unpredictable.

The amount of direction or guidance presented and the presence or absence of working examples:

In the instant case, no working examples are presented in the specification as filed showing how to prevent a thrombotic condition or disorder totally, absolutely, or permanently. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

Genentech, Inc. v. Novo Nordisk, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test the combination in the instant claims whether preventing a thrombotic condition or disorder totally, absolutely, or permanently.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-25, 33-35 and 62-65 are rejected under 3 5 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23-25, 33-35 and 62-65 recite the limitation "inducer of a PPAR γ agonist". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said

subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-23, 25, 27-33, 35, 37, 56-62, 64, and 106-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pershadsingh (US Patent No. 6,127,394) in view of Boyer (US Patent 7,018,985 B1).

Pershadsingh teaches methods of treatment by administering to a human or vertebrate animal in need a dose of a 1,2-dithiolane derivative compound that bind to or modify the activity of peroxisome proliferator activated receptor-gamma (PPAR gamma) (column 14, lines 41-45).

Pershadsingh teaches PPAR γ agonists, namely thiazolidinedione derivatives, are capable of treating diseases including thrombosis after angioplasty, acute coronary syndromes such as unstable angina, myocardial infarction, ischemic and non-ischemic

cardiomyopathies, post-MI cardiomyopathy, and myocardial fibrosis and substance-induced cardiomyopathy (column 23, table II).

Additionally, Pershadsingh teaches administration of a combination therapy of thiazolidinedione derivatives and a drug the binds to the retinoid X receptor, namely 9-cis-retinoic acid all trans-retinoic acid (column 18, lines 1-20).

Further, Pershadsingh teaches the therapeutic agents can be delivered or administered topically, by transdermal patches, parenteral therapy including intra-dermal, intra-articular, intramuscular or intravenous (column 16, lines 9-18).

Pershadsingh does not specifically teach platelets or that the patient with thrombosis is diabetic or not.

Boyer teaches platelet adhesion and aggregation are critical events in intravascular thrombosis. Activated under conditions of turbulent blood flow in diseased vessels or by the release of mediators from other circulating cells and damaged endothelial cells lining the vessel, platelets accumulate at a site of vessel injury and recruit further platelets into the developing thrombus (column 1, lines 24-30).

It would have been obvious to one of ordinary skill in the art at the time of the invention that when delivering or administering the therapeutic agents taught by Pershadsingh that one would have been contacting the platelets in order to alleviate platelet aggregation, thrombosis, or any thrombotic conditions. The motivation, provided by Boyer, teaches that platelet adhesion and aggregation are critical events in intravascular thrombosis. Thus when treating thrombosis, or any thrombotic conditions one is in effect treating the platelets from aggregating.

Furthermore, it would have been obvious to administer a patient with thiazolidinedione derivatives for the treatment of thrombosis as taught by Pershadsingh regardless of the history of the patient or the origin of the thrombotic condition.

Claims 24, 26, 34, 36, 63 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pershadsingh (US Patent No. 6,127,394) in view of Boyer (US Patent 7,018,985 B1) as applied to claims 17-23, 25, 27-33, 35, 37, 56-62, and 64 above in further view of Höök (US Patent No. 6,413,931 B1).

Pershadsingh is discussed above.

Pershadsingh does not teach an inducer of a PPAR γ agonist, namely decorin.

Höök teaches a method of inhibiting fibrin clot formation (i.e., thrombosis) by the administration or application of the protein decorin (abstract; column 1, lines 10-13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed PPAR γ agonists capable of treating diseases associated with thrombosis as taught by Pershadsingh and used decorin as a method of treating thrombosis. The motivation, provided by Höök, teaches that decorin is used as a method of treatment for the inhibition of thrombosis.

Conclusion

Claims 17-37 and 56-65 and 106-108 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617